K120092
Page 1 of 2

APR 13 2012

510(k) Summary: PLYMOUTH™ Thoracolumbar Plate System

Company: Globus Medical Inc.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

Contact: Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs

Date Prepared: January 10, 2012

Device Name: PLYMOUTH™ Thoracolumbar Plate System

Classification: Per 21 CFR as follows:
§888.3060: Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ.
Regulatory Class: II, Panel Code: 87.

Predicate(s): TRUSS® Thoracolumbar Plate System (K092108)
SE date: August 13, 2009
Nuvasive Lateral Plate System (K091071)
SE dates: May 8, 2009

Purpose:
The purpose of this submission is to request clearance for the PLYMOUTH™ Thoracolumbar Plate System.

Device Description:
The PLYMOUTH™ Thoracolumbar Plate System consists of rigid plates of various lengths that are used with variable or fixed angle bone screws. These plates attach to the anterolateral or lateral portion of the vertebral body of the thoracolumbar spine (T1-L5). These implants are manufactured from titanium alloy, as specified in ASTM standards F136, F1295 and F1472.

Indications for Use:
The PLYMOUTH™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

Performance Data:
Mechanical testing (static and dynamic compression bending and static torsion) was conducted in accordance with "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s", May 3, 2004 to demonstrate substantial equivalence to the predicate system.

Basis of Substantial Equivalence:
The PLYMOUTH™ Thoracolumbar Plate System is similar to the predicate devices with respect to technical characteristics, design, materials, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Globus Medical Incorporated
% Ms. Sarah Marie Fitzgerald
Project Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

APR 13 2012

Re: K120092
Trade/Device Name: PLYMOUTH™ Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 19, 2012
Received: March 20, 2012

Dear Ms. Fitzgerald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120092

Device Name: PLYMOUTH™ Thoracolumbar Plate System

Indications:

The PLYMOUTH™ Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE ON THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120092